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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,715	06/18/2001	Mark Pines	CGD-004.0P-U	7532

7590 01/06/2005

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EXAMINER

KWON, BRIAN YONG S

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/762,715	PINES ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brian S Kwon	1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24,25 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24,25 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1614

## **DETAILED ACTION**

### ***Status of Application***

1. Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114. Claims 24, 25 and 28 are currently pending for prosecution on the merits.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1614

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 24, 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pines et al. (US 5449678 A), and further in view of Ramieres et al. (Journal of Molecular and Cellular Cardiology, 1998, abstract, 30(3), pp. 475-83) and/or Crawford et al. (Circulation Research, 1994, abstract, (4), pp. 727-39).

Pines'678 teaches the use of quinazolinone containing composition (e.g., halofuginone) for treating or preventing fibrotic disorders such as myocardial fibrosis by inhibiting collagen type I synthesis (col. 5, lines 13-16; col. 6, line 4). The reference also teaches that halofuginone inhibits collagen type I synthesis at transcription level, regardless of the tissue or animal species (column 22, lines 23-26).

Ramieres et al. (Journal of Molecular and Cellular Cardiology, 1998, abstract, 30(3), pp. 475-83) and/or Crawford et al. (Circulation Research, 1994, abstract, (4), pp. 727-39) is(are) being supplied herein to demonstrate that the chronic administration of angiotensin II leads to myocardial fibrosis and animal models for the disease are known in the art.

As discussed above, although Pine's 678 teaches the utility of halofuginone in inhibiting collagen type I synthesis, thereby treating or preventing myocardial fibrosis, the reference does not specifically state that the subject exposed to the promoter of cardiac fibrosis such as the elevated angiotensin II, particularly prior to the subject exhibits a cardiac fibrotic condition, is susceptible to the administration of said composition. However, one having ordinary skill in the art at the time of the invention was made would have known that the enhanced activity of angiotensin II induces myocardial fibrosis in animal and myocardial fibrosis can be generated in

Art Unit: 1614

lab animals in several ways including the administration of angiotension II. Thus, one having ordinary skill in the art would have expected that the subject has been exposed to the chronic administration of angiotensin II would be benefited from the administration of halofuginone, for the ultimate purpose of treating or preventing myocardial fibrosis.

As discussed above, the prior art does not disclose that whether the administration of said composition is useful in the subject exposed to the promoter of cardiac fibrosis such as the elevated angiotensin II, particularly before the subject exhibits a cardiac fibrotic condition. However, the fact that the applicant may have discovered treatment recipient group, namely “the subject has been exposed to a promoter of cardiac fibrosis and the step of administering the compound is before the subject exhibits a cardiac fibrotic condition”, is not considered patentably distinctive over the prior art which are directed to the same ultimate therapeutic application (for the treatment or prevention of myocardial fibrosis).

### Conclusion

3. No Claim is allowed.
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

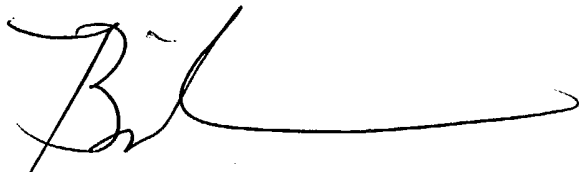
Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Application/Control Number: 09/762,715

Page 5

Art Unit: 1614

Brian Kwon  
Patent Examiner  
AU 1614

A handwritten signature in black ink, appearing to be 'BK' followed by a long horizontal flourish.